

REMARKS

Status of the claims

Claims 23-29 and 41 are pending in the application. Claim 41 is withdrawn from consideration. Claim 26 is amended. Claims 23-29 are rejected. Claims 1-22 and 29-41 are cancelled.

Claim amendments

Claim 26 has been amended to overcome rejections under 35 U.S.C. § 112, first paragraph. No new matter is added in any claim amendment. Claim 26 is amended to delete the words 'prophylaxis' and 'or a neoplastic disease' to limit this claim to the subject matter pertaining to the specification. Claim 29 is cancelled to overcome rejections under 35 U.S.C. § 112, first paragraph. Claim 41 was withdrawn from consideration because it is drawn to non-elected invention. Claim 41 is cancelled herein.

Claim objection

Claim 41 is objected to as being a non-elected invention. Claim 41 is cancelled herein. Accordingly, the Applicants respectfully request that the objection to claim 41 be withdrawn.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 23-29 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Applicants respectfully traverse this rejection.

The Examiner states that the specification does not recite a method for using compounds of the formula in claim 23 as a prophylactic agent to prevent activation of antigen-specific T cells or an autoimmune disorder or a neoplastic disease. The Examiner further states that the claims are drawn to methods of using compounds of the formula in claim 23, which are neither enabled nor supported in the specification.

Applicants submit that claim 26 is amended to delete the word 'prophylaxis'. This amendment limits the claim to a method of treatment of said disease[[s]] and disorder[[s]]using compounds of the formula in claim 23 and excludes prophylactic use of the compounds. The Applicant further submits that the specification provides many examples to demonstrate the therapeutic use of the compounds to inactivate antigen-specific T cells and thus provides sufficient data to enable one skilled in the art to use these compounds in the treatment of autoimmune disease[[s]]. Furthermore example 11, teaches the ability of the compounds to induce unresponsiveness in an alloantigen specific T cell. Thus, example 11 clearly provides for a method of treating an autoimmune disorder resulting from an allograft transplantation rejection. It is known in the art that antigen-specific T cells are activated in both an allograft and a xenograft transplantation rejection. Accordingly, the Applicants submit that the method in

example 11 can be easily extrapolated for treatment of disorder[[s]] that may result from a xenograft transplantation rejection.

Claim 29 is cancelled and claim 26 is amended to exclude treatment of neoplastic diseases using the compounds of the formula in claim 23 as a specific method for treatment of said diseases is not explicitly recited in the specification.

In view of the above, Applicants respectfully request that the rejection of claims 23-29 under 35 U.S.C. § 112, first paragraph, be withdrawn.

Rejections under 35 U.S.C. § 102(b)

Claims 23-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by (1) **Kotelko** et al. Acta Poloniae Pharmaceutica (1973), 30(2), 135-43; or (20) **Kadlubowski**, Wiadamosci parazytologicine (1978), 24(5), 575-9. The Applicants respectfully traverse this rejection.

The Examiner states that **Kotelko** et al. discloses a compound butanamide, N-[3-94-morpholiny]propyl]- which anticipates the compounds defined by the formula of claim 23 and furthermore this compound is a potential pharmacological agent. The Examiner further states that **Kadlubowski** discloses a compound Butanoic acid, 2-(4-morpholiny)ethyl ester, which anticipates the compounds defined by the formula of claim 23.

Applicants claim 23 is directed to a method of inactivating antigen specific T cells to treat an autoimmune disease or disorder using compounds of the formula recited. The Applicants are not claiming the compounds of the

formula of claim 23 per se. Furthermore neither **Kotelko** and **Kadlubowski** disclose a method of inactivating antigen-specific T cells in an individual by administering an effective amount of a compound of structure of the formula of claim 23. Accordingly, the rejection of claims 23-29 under 35 U.S.C. §102(b) is obviated. The Applicants respectfully request that the rejection of claims 23-29 under 35 U.S.C. § 102(b) be withdrawn.

Rejections under 35 U.S.C. § 103(a)

Claims 23-29 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over **Kotelko** et al., Acta Poloniae Pharmaceutica (1973), 30(2), 135-43. Claims 23-29 stand rejected under 35 U.S.C. §103(a) as being unpatentable over **Kadlubowski**, Wiadamosci parazytologicine (1978), 24(5), 575-9. The applicants respectfully traverse this rejection.


The Examiner states that **Kotelko** et al. discloses a compound butanamide, N-[3-94-morpholiny]propyl]-, which can be used as a pharmacological agent. The Applicants submit that the potential use of a compound as a pharmacological agent is very broad in its scope and does not encompass a specific method for treating a specific disease. The Applicants, submit that the claimed invention specifically targets inactivation of antigen specific T cells for treating an autoimmune disease or disorder. **Kotelko** et al. does not teach or suggest a method of inactivating antigen-specific T cells in an individual by administering an effective amount of a compound of structure of the formula of claim 23.

Kadlubowski discloses a compound Butanoic acid, 2-(4-morpholinyl) ethyl ester which has a potential antiparasitic agent. Thus, at best, **Kadlubowski** teaches a method of treating a parasitic infestation with the compound. **Kadlubowski** does not teach or suggest a method of inactivating antigen-specific T cells in an individual by administering an effective amount of a compound of structure of the formula of claim 23. In view of the above, the Applicants respectfully request that the rejection of claims 23-29 under 35 U.S.C. § 103(a) be withdrawn.

This is intended to be a complete response to the Office Action mailed June 10, 2005. Applicants submit that claims 23-28 are in condition for allowance and respectfully request that claims 23-28 be passed to issuance. If any issues remain outstanding, the Examiner is respectfully requested to telephone the undersigned attorney of record for immediate resolution. Should any fees be due, please debit Deposit Account No. 07-1185 upon which the undersigned attorney is allowed to draw.

Respectfully submitted,

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